Supreme Court, U.S.
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In The
Supreme Court of the United States

SOUTH CAROLINA MEDICAL ASSOCIATION, *et al.*,

Petitioners,

v.

TOMMY G. THOMPSON, SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

PETITION FOR A WRIT OF CERTIORARI

TERRY E. RICHARDSON, JR.*
DANIEL S. HALTIWANGER
RICHARDSON, PATRICK, WESTBROOK & BRICKMAN
P.O. Box 1368
Barnwell, South Carolina 29812
(803) 541-7850

RICHARD J. LAZARUS
GEORGETOWN UNIVERSITY LAW CENTER
600 New Jersey Ave., N.W.
Washington, D.C. 20001
(202) 662-9129

Counsel for Petitioners

* *Counsel of Record*

103 pp

QUESTIONS PRESENTED

Section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. § 1320d-2 note(c)(1), mandates that the Secretary of Health and Human Services (Secretary) promulgate standards governing "the privacy of individually identifiable health information transmitted in connection with" specified transactions in the event that Congress failed to enact "legislation governing [such] standards" within three years of HIPAA's enactment. The questions presented are:

1. Whether Article I, § 1 of the U.S. Constitution, which vests legislative power exclusively in Congress, bars Congress in HIPAA from transferring to the Secretary the legislative authority to enact medical privacy standards if, after three years, Congress is unable to enact those standards itself because they are too controversial.

2. Whether the Secretary's medical privacy standards are unlawful because they apply to all forms of individually identifiable health information and therefore exceed the scope of rulemaking authority conferred by Congress in HIPAA, which expressly limits the application of the Secretary's privacy standards to such identifiable health information only when "transmitted in connection with" nine statutorily specified electronic transactions.

PARTIES TO THE PROCEEDING

The South Carolina Medical Association, Physicians Care Network, J. Capers Hiott, M.D., John R. Ross, M.D., Gordon E. Pennebaker, M.D., Carol S. Nichols, M.D., Dannette F. McAlheny, M.D., Herbert Moskow, M.D., and the Louisiana State Medical Society were all appellants in the Fourth Circuit below. Tommy G. Thompson, in his official capacity as Secretary of Health and Human Services, and the United States Department of Health and Human Services were appellees below.

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OPINIONS BELOW

The opinion of the Fourth Circuit is reported at 327 F.3d 346 and reproduced in the appendix hereto ("App.") at A1. The opinion of the district court is unreported and is reproduced at App. A18.

JURISDICTION

The judgment of the Fourth Circuit was entered on April 25, 2003. App. A1. This Court has jurisdiction to issue the requested writ of certiorari pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

Article 1, § 1, of the U.S. Constitution, is reproduced at App. A42. Sections 261, 262, and 264 of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, 2021, 2034 (1996), codified at 42 U.S.C. §§ 1320d through 1320d-8, and §§ 1320d note, 1320d-2 note, are reproduced at App. A42-A62. The Secretary's definition of "protected health information," 45 C.F.R. § 160.103 (2003), is reproduced at App. A62-A63.

INTRODUCTION

During the 1990s, Congress repeatedly struggled to address a controversy of enormous importance to millions of Americans: the extent to which their personal medical records should be deemed private and not subject to disclosure without their permission. The issue became especially pressing during that decade because of then-rising demands for disclosure of such medical records by private and public entities who, relying on the potential ease of electronic transmissions, contended they could beneficially use the records to further important public purposes, including safeguarding public health, promoting medical research, reducing medical costs, enhancing accountability, investigating fraud, and assisting law enforcement.

Because, however, of fundamental conflicts regarding how the balance should be struck between personal privacy and these other competing social policy objectives,

Congress was unable to enact any legislation that announced standards governing the possible disclosure of personal medical records. In session after session, members of Congress introduced bills, committees held hearings, but the necessary compromises proved elusive.

Congress ultimately chose to break the legislative logjam, but did so in a patently unconstitutional manner that has set a dangerous legislative precedent that warrants this Court's plenary review. In the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996), Congress effectively imposed on itself a three-year deadline to enact standards governing medical privacy. Congress made that deadline enforceable by mandating that the Secretary of Health and Human Services (Secretary) promulgate medical privacy standards for certain transactions in the event that Congress failed to meet its own deadline. In short, Congress sought by HIPAA's express terms and deliberate design to accomplish precisely what Article I, § 1 of the U.S. Constitution provides cannot be done: transfer to the executive branch the authority to enact legislation in the event that the democratic legislative processes failed to produce a result.

The medical privacy standards since promulgated by the Secretary, moreover, underscore the constitutional pitfalls of Congress's misguided abdication of legislative responsibility. Although HIPAA made absolutely no effort to provide any intelligible principle to guide the Secretary's decision concerning how the difficult policy balance should be struck in the fashioning of federal medical privacy standards, HIPAA at least limited the Secretary's legislative purview to a series of specifically-listed electronic transactions of medical records. The Secretary's final regulations, however, even abandoned

that statutory bound, concluding that public policy warranted medical privacy standards no matter what their form or their method of transmission. The Secretary, therefore, made even more complete Congress's unconstitutional delegation of legislative authority to the executive branch by wholly untethering the rulemaking from even the most limited congressional guideposts. The regulatory upshot is a medical privacy regulation that portends revolutionary changes in the medical profession and the privacy of American citizens, which requires expenditures of billions of dollars for compliance and which authorizes widespread disclosure of private medical information in the absence of patient consent.

Petitioners, the South Carolina Medical Association, Louisiana Medical Society, and six individual doctors filed in federal district court a lawsuit challenging the constitutionality of HIPAA's delegation of legislative authority to the Secretary and the legality of the Secretary's medical privacy standards. The district court dismissed the lawsuit and the court of appeals affirmed.

STATEMENT

Statutory and Regulatory Background. In 1996, Congress passed HIPAA. The purpose of Subtitle F of HIPAA, entitled "Administrative Simplification," was "to improve the Medicare program ***, the Medicaid program ***, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." HIPAA, § 261, 110 Stat. 2021; 42 U.S.C. § 1320d note. Prior to HIPAA's enactment, there were as many as 400 different electronic formats being used for health care forms, resulting in gross inefficiencies. Subpart F sought to create one uniform

language for electronic transmission of standard health insurance information. See 65 Fed. Reg. 82463 (2000).

To that end, Section 262 of HIPAA added a new Part C, also entitled "Administrative Simplification," to Title XI of the Social Security Act. See 110 Stat. 2021-2031. Part C in turn included nine separate statutory provisions, Sections 1171-1179, which, *inter alia*, defined the relevant statutory terms (Section 1171), established requirements for the adoption of standards (Section 1172), described the relevant standards to be promulgated (Section 1173), and established relevant timetables, enforcement programs, and federal preemption policies. (Sections 1174-1179). See 42 U.S.C. §§ 1320d - 1320d-8.

Of particular relevance to the instant case, Section 1173(a) empowered the Secretary to adopt "standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically." See 42 U.S.C. § 1320d-2(a)(1). Section 1173(a) further listed nine different specific electronic transactions to which the Secretary's standards would apply.[1]

HIPAA also reflected congressional awareness of the substantial personal privacy implications of enabling electronic transmissions of medical records. Standardization of the features of medical records kept in electronic form necessarily made their disclosure that much easier and the need for privacy standards that much more pressing. At the time of HIPAA's enactment,

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[1] The listed transactions include:
(A) Health claims or equivalent encounter information. (B) Health claims attachments. (C) Enrollment and disenrollment in a health plan. (D) Eligibility for a health plan. (E) Health care payment and remittance advice. (F) Health plan premium payments. (G) First report of injury. (H) Health claim status. (I) Referral certification and authorization.
42 U.S.C. § 1320d-2.

Congress had tried for several years, without success, to enact applicable medical privacy standards. Legislators were unable to forge the necessary compromises between privacy advocates and those seeking greater disclosure of medical records. See pages 11-14, *infra*.

To break the legislative deadlock and to ensure that some standards would be in existence by the time that the Secretary's regulations designed to enable electronic transmission of medical records became effective, Section 264(a) of HIPAA instructed the Secretary to provide Congress within one year "detailed recommendations on standards with respect to the privacy of individually identifiable health information." 110 Stat. 2033; 42 U.S.C. § 1320d-2 note(a). Section 264(c) further provided that if Congress failed within three years to enact standards "with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by [HIPAA] section 262)," then the Secretary "shall promulgate final regulations containing such standards." 110 Stat. 2033; 42 U.S.C. § 1320d-2note(c).

The Secretary's Rulemakings. Pursuant to Section 1173 of the Social Security Act, as added by Section 262 of HIPAA, the Secretary has since issued proposed and final rules intended to facilitate the electronic transmission of medical records by standardizing their format and other features. The Secretary has confined the scope of each of these rulemakings to the nine transactions specifically listed in Section 1173. See, *e.g.*, Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334, 8342 (2003); Health Insurance Reform: Standards: 65 Fed. Reg 50312 (2000); Health Insurance Reform: Standards for Electronic Transactions, 63 Fed. Reg. 25272, 25320 (1998); Health Insurance Reform: National Standard Employer Identifier, 63 Fed. Reg. 32784 (1998); Security and Electronic

Signature Standards, 63 Fed. Reg. 43242 (1998).

The Secretary did not, however, likewise confine the medical privacy standards challenged in this litigation either to the nine transactions listed in Section 1173(a) or to their electronic transmission. In the December 2000 final rulemaking, the Secretary decided to "expand the definition of protected health information to encompass all individually identifiable health information transmitted or maintained by a covered entity, regardless of form." 65 Fed. Reg. 82462, 82496 (2000); see 65 Fed. Reg. 82618 (2000); 45 C.F.R. § 160.103 (2003) ("transmitted or maintained in any * * * form or medium").

The final regulations, in this respect, departed significantly from the Secretary's proposed regulations. In the proposed rulemaking, "only those providers who engage in the electronic administrative simplification transactions [were] covered * * *. Any provider who maintains a solely paper information system would not be subject to these privacy standards." 64 Fed. Reg. 59918, 59923 (1999). While the rulemaking commentary accompanying that far more limited proposal asserted that the Secretary possessed more authority than exercised in the proposed rules, the Secretary acknowledged that "the HIPAA legislative authority is more limited in scope * * * and does not always permit us to propose the policies that we believe are optimal." *Id.* According to the Secretary, "the HIPAA limits the application of our proposed rule to health plans, health care clearinghouses, and to any health care provider who transmits health information *in electronic form* in connection with transactions referred to in section 1173(a)(1) of the [Social Security] Act." *Id.* (emphasis added).[2]

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[2] The Secretary has undertaken several subsequent administrative actions extending the effectiveness and compliance dates of the December 2000 privacy standards and has also modified the

Proceedings Below. Petitioners, two state medical associations, a network of health care providers, and six physicians, filed a complaint in federal district court, based on the Constitution, 28 U.S.C. §§ 1331, 1337, 2201, challenging the constitutionality of HIPAA's delegation of lawmaking authority to the Secretary and to the legality of the Secretary's privacy standards under HIPAA. Petitioners contended that HIPAA violated the nondelegation doctrine by conferring legislative authority on the Secretary. Petitioners further alleged that the privacy standards exceeded the scope of the Secretary's statutory authority by extending those standards to all personal medical records whatever their form or method of transmission, including both paper and electronic.

The district court dismissed the complaint. App. A18. The court ruled that HIPAA provided a sufficient limitation on the Secretary's discretion to avoid offending nondelegation doctrine concerns. *Id.* at A26-A29. The district court also rejected petitioners' second contention upon concluding that the plain meaning of HIPAA supported the Secretary's interpretation that the statute authorized promulgation of medical privacy standards applicable to all personal medical records. *Id.* at A29-A32.

The court of appeals affirmed. App. A1. On the nondelegation issue, the court concluded that HIPAA announced a "general policy" that guided the Secretary's lawmaking authority to an extent sufficient to satisfy the nondelegation doctrine and that Congress had effectively agreed to the standards by default -- by not enacting legislation that formally objected to the Secretary's recommendations. *Id.* at A8-A11. With regard to the scope of the Secretary's lawmaking authority under

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standards in some respects not relevant to the issues raised in this case. See 66 Fed. Reg. 12434 (2001); 66 Fed. Reg. 12738 (2001); 67 Fed. Reg. 53182 (2002).

HIPAA, the appellate court further held that "the plain language of HIPAA indicates that HHS could reasonably determine that the regulation of individually identifiable health information should include non-electronic forms of that information." *Id.* at A12-A13.

REASONS FOR GRANTING THE WRIT

This petition presents two legal issues warranting this Court's review. First, the Secretary of HHS promulgated medical privacy regulations pursuant to an improper congressional transfer to the Secretary of legislative lawmaking authority that violates Article 1, § 1, of the United States Constitution. By deliberate congressional design, HIPAA assigns to the Secretary the exclusive responsibility of legislating by rulemaking medical privacy standards in the event that Congress is unable to enact such standards within three years. The Constitution does not countenance such a blatant reallocation of legislative authority to the executive branch whenever Congress concludes that a policy matter of fundamental importance to millions of Americans and the health care profession is too difficult and controversial for Congress to handle.

Second, in subsequently promulgating medical privacy standards, the Secretary ignored the only clear guidance that Congress did provide in HIPAA, which was to restrict the scope of the privacy standards to electronic transmissions associated with nine statutorily-listed transactions. The Secretary thereby exceeded the scope of the delegation of authority Congress intended to confer. This second error not only provides an independent legal error warranting invalidation of the regulations, but also further underscores HIPAA's violation of the nondelegation doctrine. If, as the Secretary claims, HIPAA does provide the Secretary with authority to extend its

medical privacy regulations essentially to all medical records, then such a massive delegation would have made it all the more necessary that it be accompanied by the constitutionally required "intelligible principle" sufficient to guide the Secretary's exercise of such lawmaking authority. Here, however, there was none.

Review is warranted even though the court of appeals below is the first to consider the constitutionality of HIPAA and the lawfulness of the Secretary's medical privacy standards. The extraordinary breadth and depth of those standards implicate the core personal autonomy and privacy rights of millions of Americans and they are at this moment requiring hundreds of thousands of health care providers to change dramatically their services, at a cost of billions of dollars. By the Secretary's own accounting, the regulations directly apply to 12,200 health plans, 6480 hospitals, and 630,000 non-hospital providers, including 562,916 small businesses and individual physicians. 65 Fed. Reg. 82765, 82779 (2000). Although invariably touted as promoting patient privacy, the Secretary's regulations in fact authorize disclosure of historically confidential patient information in a variety of circumstances, including to government officials without a warrant, and without the patient's consent. In such extreme circumstances, prudence justifies the Court's departing from its normal practice of delaying review for several years to allow further lower court litigation. The petition should instead be granted.

I. REVIEW OF THE NONDELEGATION DOCTRINE ISSUE IS WARRANTED

"In a delegation challenge, the constitutional question is whether the statute has delegated legislative power to the agency. Article I, § 1 of the Constitution * * * permits no delegation of those powers." Whitman v. American

Trucking Ass'n, 531 U.S. 457, 472 (2001). "Congress manifestly is not permitted to abdicate, or to transfer to others, the essential legislative functions with which it is thus vested." Panama Refining Co. v. Ryan, 293 U.S. 388, 421 (1935). This Court has, accordingly, repeatedly held "that when Congress confers decisionmaking authority upon agencies *Congress* must 'lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform'" American Trucking Ass'n, 531 U.S. at 472, quoting J. W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928).

In HIPAA, Congress blatantly abdicated its legislative authority in violation of the nondelegation doctrine. HIPAA Section 264(c) expressly instructed the Secretary to promulgate medical privacy standards in the event that Congress proved unable to meet its own deadline for doing so. Hence, Congress expressly predicated its transfer of legislative responsibility to the Secretary on Congress's failure to pass legislation that might, at the very least, have provided the Secretary with the "intelligible principle" required to render such an allocation of lawmaking authority constitutional.

The reasons for Congress's abdication of legislative responsibility are plain. Determining what factors should be relevant to the fashioning of medical privacy standards and their relative weight in the balancing necessary for their application is complex and controversial. Lawrence O. Gostin, James G. Hodges, Jr., *Personal Privacy and Common Goods: A Framework for Balancing Under National Health Information Privacy Rule*, 86 Minn. L. Rev. 1439, 1454 (2002). "Hard choices" must be made in deciding whether we should "sharply limit the systematic collection of identifiable health care data in order to achieve reasonable levels of informational privacy" or "decide that the value of information collection is so important to the

achievement of societal aspirations for health that the law ought not promise absolute or even significant levels of privacy at all * * *." Lawrence O. Gostin, *Health Information Privacy*, 80 Cornell L. Rev. 451, 455 (1995).

What happened prior to and in the aftermath of HIPAA's enactment is that the hard choices presented by fashioning medical privacy standards became a "political hot potato" that Congress preferred to toss to the Secretary. Charity Scott, *Is Too Much Privacy Bad for your Health? An Introduction to the Law, Ethics, and HIPAA Rule on Medical Privacy*, 17 Ga. St. U. L. Rev. 481, 481 (2000). "[V]arious competing interests and starkly different views over where we should strike the appropriate ethical balance * * * stymied all efforts to pass such federal legislation." *Id.* at 505. "About a half dozen policy questions * * * apparently prove[d] intractable in the congressional debates." *Id.* at 513.

In the months just before the HIPAA deadline, multiple bills were pending in the House[3] and Senate,[4] with

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[3] See H.R. 1057, Medical Information Privacy and Security Act, 106th Cong., 1st Sess. (1999); H.R. 1941, Health Information Privacy Act of 1999, 106th Cong., 1st Sess. (1999); H.R. 2404, Personal Medical Information Protection Act of 1999, 106th Cong., 1st Sess. (1999); H.R. 2878, Medical Privacy in the Age of New Technologies Act of 1999, 106th Cong., 1st Sess. (1999).

[4] S. 573, Medical Information Privacy and Security Act of 1999, 106th Cong., 1st Sess. (1999); S. 578, Health Care Personal Information Nondisclosure Act of 1999, 106th Cong., 1st Sess. (1999); S. 881, Medical Information Protection Act of 1999, 106th Cong., 1st Sess. (1999); see also S. 2129, Health Care Privacy Protection Act, 103rd Cong., 2d Sess. (1994); S. 1360, Medical Records Confidentiality Act, 104th Cong., 1st Sess. (1995); S. 1368, Medical Information Privacy and Security Act, 105th Cong., 1st Sess. (1997); S. 2352. Patient Privacy Rights Act of 1998, 105th Cong., 2d Sess. (1998); S. 2609, Medical Information Protection Act of 1998, 105th Cong., 2d Sess. (1998);

extensive hearings held in both chambers.[5] None passed. As later described by Senator Patrick Leahy, a major sponsor of pending legislation, "We couldn't do the job on our own and we have instead shifted the responsibility to the administration." 146 Cong. Rec. S 6186 (2000).[6] Then-Secretary Donna Shalala similarly described the relationship between Congress and the executive branch in her press conference announcing her medical privacy standards: "*Congress tried to write these regulations and they actually couldn't get it done, they couldn't find a consensus to get it finished.*" J.A. 272 (emphasis added).[7] Finally, in announcing the Secretary's proposed medical privacy standards, President Clinton likewise commented that the

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[5] See, *e.g.*, *Confidentiality of Individually Identifiable Health Information*, Hearing before the Sen. Comm. on Labor and Human Resources, 106th Cong., 2d Sess. (1998); *Patient Confidentiality*, Hearing before the Subcomm. on Health of the House of Representatives Ways & Means Comm., 106th Cong., 2d Sess. (1998); *The Consumer Protection and Medical Confidentiality Act of 1998*, Hearing before the Subcomm. on Government Management, Information and Technology of the House of Representatives Comm. on Government Reform and Oversight, 106th Cong., 2d Sess. (1998); *Confidentiality of Medical Information*, Hearing before the Senate Comm. on Health, Education, Labor and Pensions, 107th Cong., 1st Sess. (1999); *Medical Records Confidentiality in the Modern Delivery of Health Care*, Hearing before the Health and Environment Subcomm. of the House of Representatives Comm. on Commerce, 107th Cong., 1st Sess. (1999); *Confidentiality of Patient Records*, Hearing before the Subcomm. on Health of the House of Representatives Ways & Means Comm., 107th Cong., 2d Sess. (2000).

[6] But the Senator simultaneously acknowledged the impropriety of such a shift: "This Congress has the responsibility to protect the privacy of Americans - and that includes protection of their medical records. The place for these protections is in legislation - not regulation." 146 Cong. Rec. S 6186; see *id.* at E 2307 (remarks of Rep. Condit) ("Congress failed to act on this crucial issue.").

[7] "J.A." refers to the joint appendix filed in the court of appeals.

reason for executive branch action was congressional default. See J.A. 261 ("I am taking this action today because Congress failed to act, and because a few years ago Congress explicitly gave me the authority to step in if they were unable to deal with this issue.").

Political convenience was therefore clearly the motive for congressional abdication in HIPAA, but it is equally clear that "the fact that a given law or procedure is efficient, convenient, and useful in facilitating functions of government, standing alone, will not save it if it is contrary to the Constitution." Immigration and Naturalization Service v. Chadha, 462 U.S. 919, 944 (1983). "[P]olicy arguments supporting even useful 'political inventions' are subject to the demands of the Constitution which defines powers and * * * sets out just how those powers are to be exercised." *Id.* at 945. "That a congressional cession of power is voluntary does not make it innocuous. * * * Abdication of responsibility is not part of the constitutional design." Clinton v. City of New York, 524 U.S. 417, 452 (1998) (Kennedy, J., concurring). Where there are "hard choices" to be made, and where issues are "politically so divisive that the necessary decision or compromise [is] difficult, if not impossible, to hammer out in the legislative forge," it is that much *more*, not *less*, important under our Constitution that the decisions are ultimately "made by the elected representatives of the people * * * [and] the buck stops with Congress." Industrial Union Dept. v. American Petroleum Institute, 448 U.S. 607, 687 (1980) (Rehnquist, J., concurring).

Nor is there any merit to the court of appeals' conclusion (App. A8) that HIPAA otherwise provided the "intelligible principle" necessary to convert an improper delegation of legislative responsibility into a constitutional assignment of executive branch rulemaking authority pursuant to a federal statute. HIPAA provides no such

"intelligible principle." To constitute an intelligible principle under this Court's precedent, a congressional enactment must, at a bare minimum, identify the substantive factors relevant in fashioning a regulation. In some circumstances, the statute should go further and provide some guidance concerning how the agency should procedurally and/or substantively strike the balance between competing considerations. The precise level of congressional guidance necessary in a particular context depends on the breadth of the regulations at issue. As described by this Court in *Whitman v. American Trucking Ass'n*, "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." 531 U.S. at 475. For "setting * * * standards that affect the entire national economy," such as the Secretary's medical privacy standards, Congress "must provide substantial guidance." *Id.*

HIPAA, however, not only fails to provide the constitutionally required "substantial guidance," it fails to provide any meaningful guidance at all. HIPAA mandates the Secretary's promulgation of medical privacy standards if Congress fails to do so, but without offering the barest suggestion of the substantive factors relevant to their promulgation, let alone any guidance concerning how to strike a balance between them. Privacy in the medical context is exceedingly important, but like other ethical values, it is not absolute and is subject to qualification. Yet, in HIPAA, Congress never provides the Secretary with even the most minimal guidance concerning what factors should be relevant in assessing the privacy concerns implicated by particular medical records or what factors should be relevant in assessing the social policy objectives allegedly favoring disclosure of those records. Even more particularly, Congress never addresses: (1) What factors the Secretary should consider in determining

the scope of medical privacy rights that an individual should have; (2) What factors the Secretary should consider in determining what procedures an individual should have for exercising those rights; or (3) What factors the Secretary should consider in determining what uses and disclosures of that information should be authorized.

The court of appeals' fundamental error was its mistaking for an intelligible principle in HIPAA the presence in the Act of some congressional guidance as to the scope of the medical privacy standards. We do not deny that HIPAA provides some such statutory bounds. Indeed, as we argue in Part II below, the Secretary's privacy standards are separately flawed because they ignore those express bounds. But the fact that rulemaking authority has some outer bounds is not the constitutional equivalent of an intelligible principle for exercising the lawmaking authority *within* those established bounds, let alone the "substantial guidance" necessary in this case in light of the extraordinary breadth and depth of the Secretary's medical privacy standards.

Hence, HIPAA's provision (Section 264, 42 U.S.C. §1320d-2 note(b)) that the standards should "at least" cover (1) "The rights that an individual who is a subject of individually identifiable health information should have"; (2) "The procedures that should be established for the exercise of such rights" and (3) "the uses and disclosures of such information that should be authorized or required" falls nowhere near the applicable constitutional standard. Wholly missing from the statute is any substantial congressional guidance regarding how the Secretary is to determine what those individual "rights" should be or what "disclosures * * * should be authorized or required." Indeed, even this purported legislative guidance provides no bounds because, HIPAA merely provides that the standards must "at least" cover these

topics. *Id.*

No more persuasive is the lower court's additional reliance (App. A8-A9) upon either the preamble statement in HIPAA Section 261 regarding HIPAA's general purpose or the fact that HIPAA's privacy standards are limited "to communications of listed information by particular covered entities." Section 261's preamble statement provides absolutely no guidance for the Secretary concerning how individual rights should be protected or to what extent. It is merely a general preamble statement applicable to the entire statute and of no special legal import. See Panama Refining, 293 U.S. at 418. Nor does the fact that HIPAA's privacy standards are limited to individually identifiable health information by certain entities excuse Congress from providing the Secretary with guidance on how to determine privacy standards for such crucial personal information.[8]

Indeed, this Court's recent decision in *Whitman v. American Trucking Ass'n* is illustrative of both the failings of HIPAA and the lower courts' misapplication of this Court's nondelegation doctrine precedent. In *American Trucking*, the Court rejected a nondelegation challenge to the EPA Administrator's promulgation of a national ambient air quality standard pursuant to the Clean Air Act, 42 U.S.C. §§ 7407-7409. The Court concluded that the Clean Air Act provided the necessary "intelligible principle" because the Act both identified the factors relevant and not relevant to the Administrator's selection of a standard and instructed the Administrator how the

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[8] To be sure, where, unlike in HIPAA, Congress has delegated to an agency the narrow task of defining a technical term of limited application, no further guidance may be necessary. See *American Trucking Ass'n*, 531 U.S. at 574 (comparing minimal legislative guidance necessary for agency definition of a "country elevator" to "substantial guidance" necessary for national air quality standards).

balance should be struck. The Act made plain that economic compliance costs were irrelevant to standard setting, which should consider only public health risks, and that the Administrator should set the air quality standards at a level "requisite" or "sufficient, but not more than necessary" to protect public health. 531 U.S. at 473.

However, under the Secretary's view, endorsed by the court of appeals below, it would presumably have been sufficient in *American Trucking* had the Clean Air Act simply mandated the Administrator's promulgation of national air quality standards, without more. So long as the federal statute provided some jurisdictional bounds -- presumably such as "air quality" and "national standards" -- the Constitution's nondelegation doctrine would require no more. Such an extraordinary misapprehension of this Court's precedent warrants this Court's review.[9]

Nor is there any merit to the court of appeals' further suggestion that any constitutional infirmity is somehow

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[9] The other recent cases in which this Court has rejected nondelegation doctrine challenges are similarly distinguishable from this case. In *Touby v. United States*, 500 U.S. 160 (1991), the Attorney General's authority to designate "controlled substances" was sharply circumscribed to those presenting an "imminent hazard." In *Loving v. United States*, 517 U.S. 748, 772 (1996), the President's choices for determining the aggravating factors in capital cases under military law were "set within boundaries the President may not exceed." In *Mistretta v. United States*, 488 U.S. 361, 379 (1989), the U.S. Sentencing Commission did not run afoul of the nondelegation doctrine because "[t]he statute outlines the policies which prompted establishment of the Commission, explains what the Commission should do and how it should do it, and sets out specific directives to govern specific situations" and other federal statutes established applicable sentencing boundaries. Not only does HIPAA provide no comparable level of legislative guidance to the Secretary, but the reach of the Secretary's privacy standards into the daily lives of millions of Americans is far greater than the agency rules at issue in *Loving*, *Touby*, or *Mistretta*.

cured because HIPAA Section 264 called for the Secretary to promulgate medical privacy standards after first making recommendations regarding such standards to Congress. No serious claim can be maintained that such a reporting requirement bears any relevance to HIPAA's constitutionality. The court of appeals' view to the contrary - "That Congress did not enact additional measures in light of these recommendations indicates the legislature's satisfaction with HHS's proposed approach" (App. A11) - is wholly untenable.

Congress acts in only one meaningful way under the Constitution: by enacting legislation. Congressional receipt of executive branch recommendations does not amount to a legislative enactment approving or disapproving of those recommendations. Such a reporting requirement is perfectly sensible, but it is of absolutely no constitutional moment to a nondelegation challenge. Indeed, Congress's failure to enact legislation in response to those recommendations merely underscores the impropriety of HIPAA's attempt to circumvent the constitutionally demanded legislative process by purporting to assign that function to the Secretary.

Finally, any possible doubt regarding the existence of an intelligible principle in HIPAA is removed by examination of the rulemaking record itself. The Secretary published more than 700 hundred pages of preamble commentary to accompany the proposed and final rulemaking. That commentary explains in some detail why the Secretary chose to strike the balance between privacy concerns and other competing social concerns in a variety of contexts. What is striking is that in none of that explanation does the Secretary ever refer to any relevant principles established by the governing statute, HIPAA. The rulemaking record is stunningly silent, no doubt because so too is HIPAA.

The Secretary, in effect, decided entirely on her own both what the relevant factors should be and how to strike the balance between them in the final rulemaking. Wholly absent from the Secretary's reasoning was any suggestion that HIPAA guided the Secretary's balancing process in any way, let alone in the "substantial" way required by this Court's precedent.

II. REVIEW OF THE LEGALITY OF THE SCOPE OF THE SECRETARY'S MEDICAL PRIVACY STANDARDS IS ALSO WARRANTED

The Secretary's medical privacy standards, moreover, are invalid on yet a second, distinct ground. They exceed the statutory authority that HIPAA conferred on the Secretary. Although, as described above, HIPAA is itself unconstitutional under the nondelegation doctrine, Congress did make some effort at least to place outer bounds on the substantive scope of the Secretary's authority. In the final rulemaking, however, the Secretary blithely transgressed that statutory bound by promulgating medical privacy standards that apply to all personal medical records regardless of their form or their method of transmission.

"Because this case involves an administrative agency's construction of a statute that it administers, [this Court's] analysis is governed by *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)." Food & Drug Administration v. Brown & Williamson, 529 U.S. 120, 132 (2000). Under *Chevron*, "although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing 'court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Id.* at 125-126, quoting *Chevron*, 467 U.S. at 842-843. "In determining whether Congress has specifically addressed the question at issue,

a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning * * * of certain words or phrases may only become evident when placed in context." *Id.* at 132.

In this case, moreover, the Secretary is entitled to no judicial deference. The plain meaning of HIPAA's relevant language, read both in isolation and in its broader statutory context, makes clear that the Secretary does not possess sweeping lawmaking authority to enact medical privacy standards applicable to all individually identifiable health information.

It is common ground that HIPAA Section 264(c)(1) is the exclusive source of the Secretary's authority to promulgate medical privacy standards. Section 264, however, expressly limits the Secretary's standard setting authority "to the privacy of individually identifiable health information *transmitted in connection with the transactions described in section 1173(a) of the Social Security Act* (as added by section 262)" (emphasis added). Section 1173(a) in turn sets forth nine specific transactions for which the Secretary shall "adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically." Only those nine transactions are covered and, even then, only as necessary to enable their electronic transmission. Contrary to the court of appeals' ruling below, therefore, Section 264's cross-reference to Section 1173(a) expressly contradicts the Secretary's decision in the final regulations to issue privacy standards applicable to personal medical records "transmitted or maintained in any . . . form or medium." 45 C.F.R. § 160.103 (2003).

HIPAA's overall statutory structure confirms the extent of the Secretary's usurpation of legislative authority. Most strikingly, comparison of the language of Section 264(a), in which the Secretary is asked to make

privacy standard recommendations to Congress, to the language of Section 264(c), in which the Secretary is given rulemaking authority, underscores congressional intent to deny the Secretary the very sweeping authority he now claims. While Section 264(a) instructed the Secretary to provide Congress with "recommendations on standards with respect to the privacy of individually identifiable health information," without any further qualification, Congress in 264(c) expressly qualified the Secretary's rulemaking authority "to the privacy of individually identifiable health information *transmitted in connection with the transactions described in section 1173(a).*" The Secretary, however, has essentially read that express limitation on his authority out of existence.

The reason for the contrasting language in Sections 264(a) and 264(c) is also clear. The overall purpose of Section 1173(a), added by Section 262 of HIPAA, was to promote electronic transmission of health care information in the listed transactions by establishing uniform standards (*e.g.*, formats, identifiers, and data codes) for the electronic transmission of certain health information. Before HIPAA, the lack of such standardization had resulted in gross inefficiencies because there were hundreds of different (and incompatible) electronic formats. At the same time, however, as the Secretary herself explained, Congress understood that "[t]he risk of improper uses and disclosures has increased as the health care industry has begun to move from primarily paper-based information systems to systems that operate in various electronic forms." 64 Fed. Reg. 59920 (1999). Technological "advances have reduced or eliminated many of the logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals." *Id.*

It is for that reason that Congress concluded "that

privacy standards must accompany the electronic data interchange standards and that the increased ease of transmitting and sharing individually identifiable health information must be accompanied by an increase in the privacy and confidentiality." 64 Fed. Reg. 60006. Fearful that Congress would be unable to enact the privacy standards in a timely basis itself, Congress decided to allocate some interim lawmaking authority over medical privacy standards to the Secretary in the event of congressional failure to meet a three year deadline. But, in taking this dramatic step, Congress also took care to limit the Secretary's lawmaking authority over privacy standards to the electronic transmission of the same nine transactions listed in Section 1173(a) that Congress knew it was otherwise promoting in HIPAA.[10]

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[10] Significantly, the Secretary's privacy standards are the only HIPAA standards that the Secretary has sought to apply to nonelectronic forms of medical records. The Secretary is authorized to promulgate a wide array of non-privacy standards under Section 1173(a) and for none of those other standards has the Secretary sought to apply standards beyond the four corners of Section 1173(a). Instead, consistent with the plain meaning of the statutory language, the Secretary has promulgated standards applicable only to the statutorily-listed transactions and electronic transmissions. See Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334, 8342 (2003) ("While we agree that protected health information in paper or other form also should have appropriate security protections, the proposed rule proposing the security standards proposed to apply those standards to health information in electronic form only. We are, accordingly, not extending the scope in this final rule."); Health Insurance Reforms: Standards for Electronic Transactions, 65 Fed. Reg. 50312, 50318 (2000) (rejecting suggestion "that the transaction standards and their codes sets, in some manner, apply to paper transactions" because otherwise "many health care providers would revert to paper claims if the data requirements were less restrictive than those for electronic claims."); see 64 Fed. Reg. 59928 ("Our prior proposals under HIPAA have addressed only electronically

In the Federal Register commentary accompanying the proposed medical privacy standards, unlike in the final rulemaking, the Secretary recognized that HIPAA placed significant limits on the Secretary's authority to issue medical privacy standards. The Secretary expressly admitted that "the HIPAA legislative authority is more limited in scope * * *and does not always permit us to propose the policies that we believe are optimal." 64 Fed. Reg. 59923. The Secretary went on to describe how under the proposed regulation, "[a]ny provider who maintains a solely paper information system would not be subject to these privacy standards, thus leaving another gap in the system of protection we propose to create." *Id.* In the final regulations, however, the Secretary effectively ignored HIPAA's express limitations and decided unilaterally to close that "gap" by extending the privacy standards to all personal medical records, including those maintained under "a solely paper information system."

The court of appeals erred by finding support (App. A12-A13) for the Secretary's interpretation in two provisions added to the Social Security Act by HIPAA Section 261: Section 1171(6)'s definition of "individually identifiable information" and Section 1173's purpose "to enable health information to be exchanged electronically." Neither provision, however, redefines the bounds of the Secretary's standard setting authority set forth in HIPAA Section 264(c). It is neither relevant nor surprising that "individually identifiable health information" can extend for some purposes in the Social Security Act to such information in nonelectronic forms. What is dispositive is that Congress in HIPAA Section 264(a) expressly declined to confer standard setting authority on the Secretary for all such personal health information. Nor, contrary to the

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maintained and transmitted information.").

court of appeals' did Congress in Section 264(c) grant authority to the Secretary to issue privacy standards to the extent the Secretary thought such standards would "enable health information to be exchanged electronically." As previously described, Section 264(c)'s grant of agency lawmaking authority is more narrowly drawn and contains no such unbounded purpose.

No doubt that is why, prior to the final rulemaking, it was essentially common ground that the Secretary lacked any such extraordinarily expansive rulemaking authority to promulgate medical privacy standards. In her formal recommendations to Congress in 1997, the Secretary acknowledged the absence in HIPAA of the very authority she subsequently asserted in the final rulemaking. Secretary Shalala stated that HIPAA "calls for the Secretary of HHS to impose confidentiality controls on *electronic* transmission systems." J.A. 355 (emphasis added). President Clinton similarly acknowledged that further legislation would be necessary to extend privacy standards to paper transactions. J.A. 262 ("only through legislation can we cover all paper records").

The rulemaking itself even expressly acknowledges the weakness of its underlying legal argument by deliberately structuring the relevant regulation to allow for its partial invalidation with the least amount of disruption. See 65 Fed. Reg. 82496 ("We have structured the definition this way so that, if a court were to disagree with our view of our authority in this area, the rule would still be operational, albeit with respect to a more limited universe of information.").

Finally, the Secretary contended in the rulemaking that a broader assertion of jurisdiction made sense as a matter of policy because otherwise those subject to regulation might be able to avoid the privacy standards simply by avoiding electronic transmissions. See 65 Fed. Reg. 82619.

We question whether the advantages of electronic transmissions would be so easily outweighed, but in any event, the short answer is that such a policy concern is for Congress to address in the first instance. If the Secretary believes that rules of broader applicability are needed, the Secretary must persuade Congress to provide the Secretary with broader authority. In HIPAA, however, Congress has not only declined to provide such broad authority, but instead accomplished just the opposite result. In the interim, "regardless of how serious the problem an administrative agency seeks to address, * * * it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" FDA v. Brown & Williamson, 529 U.S. at 125, quoting ETSI Pipeline Project v. Missouri, 484 U.S. 495, 517 (1988).

III. REVIEW IS WARRANTED IN THIS CASE

We readily acknowledge that this Court's normal practice is not to grant review in the first case that presents a legal issue, but instead to await further litigation. The extraordinary nature of both Congress's action in HIPAA and the Secretary's rulemaking warrant a departure from that practice in this case.

Most simply put, the enormous impact of the Secretary's usurpation of legislative authority in promulgating the medical privacy standards justifies this Court's immediate attention. Any nondelegation issue implicates fundamental issues of individual liberty. "Separation of powers was designed to implement a fundamental insight: concentration of power in the hands of a single branch is a threat to liberty." Clinton v. City of New York, 524 U.S. at 450 (Kennedy, J., concurring). But, the liberty implications at stake in this litigation are magnified many fold because of the breadth, depth, and

character of the rulemaking at issue, which is likely why the Secretary received nearly 52,000 comments on the proposed regulation. 65 Fed. Reg. 82566.

As described by the Secretary herself in the final 2000 rulemaking "[t]his final rule establishes, for the first time, a set of basic national privacy standards * * *" and the rules promulgated by the Secretary "are likely the largest single federal initiative to protect privacy." 65 Fed. Reg. 82464, 82468. See J.A. 261 (remarks of President Clinton) ("the first comprehensive national standards for protection of medical records"). The Secretary's rulemaking affects the privacy rights on a matter that for millions of Americans strikes at fundamental notions of personal autonomy. The Hippocratic oath of confidentiality lies at the foundation of the doctor-patient relationship. Like other privileges, it is not absolute. But there is nothing merely technical nor incidental about fashioning a legal standard to govern the terms for its potential breach. It is instead the very kind of legal issue for which any meaningful lawmaking calling for the breach of confidentiality must be well grounded in legislation enacted by democratically elected representatives of the people. Especially because the executive branch has its own bureaucratic policies favoring disclosure, it is all the more incumbent that Congress not be circumvented, even if it seems politically expedient to do so.

However, just such a circumvention of the legislative process was, albeit at Congress's own initiative, precisely what happened pursuant to HIPAA. As a result, the personal medical records of 282 million Americans are now subject to disclosure based on privacy standards established by the Secretary not only in the absence of the constitutionally required "intelligible principle" but in blatant violation of the limited bounds established by Congress in HIPAA.

Although the Secretary touts the regulations as safeguarding patient privacy, the regulations in fact authorize widespread releases of historically confidential patient information. Under the regulations, no patient consent is frequently necessary for release of private medical information to government agencies. Hence, law enforcement officers now can often obtain ready access to personal medical records in a host of circumstances (see 45 C.F.R. § 164.512; 67 Fed. Reg. 53226-32 (2002)), which raises a distinct constitutional issue under this Court's recent ruling in *Ferguson v. City of Charleston*, 532 U.S. 67 (2001). Patient consent is similarly not necessary for releases of personal medical information that fall within the potentially open-ended category of "uses and disclosures to carry out treatment, payment, or health care operations." 45 C.F.R. § 164.506; 67 Fed. Reg. 53208-19 (2002); Richard Sobel, *A New Wound to Medical Privacy: -- Administration Rules Eviscerate Patient Consent*, L.A. Times 15 (August 23, 2002). Because, moreover, the Secretary's privacy regulations now narrowly define what constitutes "marketing," even the regulatory promise that covered entities must obtain prior patient authorization before using patient health information or disclosing it for commercial purposes often proves illusory in practice. 45 C.F.R. §§ 164.501, 164.508(a)(3); *Health Care Records: Books Open to Abuse*, TRIAL, 42 (October 2002) ("Not only do the changes define marketing in a very troubling way, but they also remove some safeguards that were in the regulation."). Whatever the merits of these sweeping decisions by the Secretary for when patient consent is not required for disclosure of quintessentially private medical information, Congress provided no guidance, let alone an intelligible principle, to guide the Secretary's lawmaking.

Finally, regulatory compliance, which is just now beginning, is requiring hundreds of thousands of large

and small medical providers to make major changes in the way they provide their services. Based on the Secretary's own analysis, "[t]here are approximately 12,200 health plans * * *, 6480 hospitals, and 630,000 non-hospital providers that will bear implementation costs under the final rule." 65 Fed. Reg. 82765. That includes 562,916 "small health care entities," including, nonprofit health plans, small physician practices, small businesses providing health coverage, and pharmacies. *Id.* at 82779.

The health care industry in the United States currently amounts to more than 13 percent of the nation's economic output. Literally billions of dollars of investments will be necessary for compliance, especially in the first few years of the privacy standard's legal effectiveness. By the Secretary's own calculations, "[t]he estimated cost of compliance with the final rule is $ 17.6 billion over the ten year period, 2003-2012." 65 Fed. Reg. 82760.[11] Other estimates predict costs as high as $40 billion for that same time period. Whatever the ultimate tally, the dollar amount will plainly not only be in the billions, but, even more importantly, will be merely a reflection of the extraordinarily far-reaching changes in individual behavior that the medical privacy standards will require, only a fraction of which were likely contemplated.[12]

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[11] Based on subsequent modifications, the Secretary has reduced the estimated costs of compliance with the privacy standards by $100 million over ten years. 67 Fed. Reg. 53182, 53259 (2002).

[12] For instance, clergy have learned that their visits to hospitals to counsel ill patients are now severely restricted. Ann Rodgers-Melnick, *Privacy Rules May Limit Clergy Hospital Visits*, Post-Gazette, http://www.post-gazette.com/healthscience/20030228hospitals4.asp (visited June 11, 2003). In a letter to the Secretary dated November 20, 2001, approximately 200 organizations and individuals, including the Association of American Medical Colleges, American Psychological Society, American Hospital Association, and virtually every major

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

TERRY E. RICHARDSON, JR.*
DANIEL S. HALTIWANGER
RICHARDSON, PATRICK, WESTBROOK & BRICKMAN
P.O. BOX 1368
BARNWELL, SOUTH CAROLINA 29812
(803) 541-7850

RICHARD J. LAZARUS
GEORGETOWN UNIVERSITY LAW CENTER
600 NEW JERSEY AVE., N.W.
WASHINGTON, D.C. 20001
(202) 662-9129

Counsel for Petitioners

* *Counsel of Record*

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medical research facility in the nation, voiced their "serious concerns" regarding the Secretary's December 2000 final rules, including how the rules would "seriously impair" research. See Ass'n of American Medical Colleges, http://www.aamc.org/advocacy/library/hipaa/corres/2001/112001.htm (visited 6/11/03). Although the Secretary has since modified the rules in some limited respects in response to the medical research community's concerns, the existence of such correspondence underscores both the practical importance of the legal issues presented and the constitutional impropriety of the Secretary's assertion of exclusive lawmaking authority over medical privacy standards in derogation of the Constitution's deliberate design.